K051839

MAR 9 2006

510(k) Summary

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The assigned 510(k) number is K051839.

Company	Abbott Diabetes Care Inc.
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Phone	510-749-6475
Contact Person:	Dhruma Shah dhruma.shah@abbott.com
Proprietary Name:	FreeStyle Freedom™ Blood Glucose Monitoring System
Common Name:	Blood Glucose Testing System
Classification Number:	21 CFR §862.1345
Predicate Device:	FreeStyle Blood Glucose Monitoring System
Date Prepared:	July 1, 2005

Description of the Device:

The FreeStyle Freedom™ monitor utilizes coulometric biosensor technology found in the FreeStyle Freedom test strip to quantitatively measure glucose concentration in whole blood samples or in FreeStyle Control Solutions. The FreeStyle Freedom BGMS measures glucose electrochemically. The glucose biosensor is capable of recognizing the glucose present in whole blood by virtue of the glucose specificity of the enzyme glucose dehydrogenase (GDH) present on the glucose test strip.

Intended Use of the Device:

The FreeStyle Freedom Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

The FreeStyle Freedom Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

Comparison to Predicate Device:

	Predicate Device	Subject (modified) Device
Company	Abbott Diabetes Care Inc	Same
510(k) Reference	K992684, K000582, K012014, K031260, K050500	Current Submission
Proprietary Name:	FreeStyle Blood Glucose Monitoring System	FreeStyle Freedom™ Blood Glucose Monitoring System
Common Name:	Blood Glucose Testing System	Same
Classification Number:	21 CFR §862.1345	Same
Intended Use	Quantitative measurement of blood glucose concentrations	Same
Single Use?	No	Same
Sterilized?	No	Same

Differences from Predicate Device

Modification Description	FreeStyle	FreeStyle Freedom
LCD size change	30.5 mm Width 27.5 mm Height	28.5 mm Width 34.5 mm Height
Alarm mode	Not included	4 programmable alarm settings
Lock unit of measure for Glucose reading	User selectable unit of measure (mg/dL or mmol/L)	Unit of measure set to either mg/dL or mmol/L at manufacturer
Glucose Measurement Assay Time	Average 7 seconds	Average 5 seconds

Performance Studies:

The performance of the FreeStyle Freedom Blood Glucose Monitoring System was evaluated in laboratory studies as well as accuracy and lay user clinical studies. Data from the clinical studies demonstrates that lay users can obtain results from the FreeStyle Freedom Blood Glucose Monitoring System that correlate well with the laboratory reference glucose values.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the FreeStyle Freedom™ Blood Glucose Monitoring System is substantially equivalent to the performance of the predicate devices for blood glucose testing and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 9 2006

Dhruma Shah
Regulatory Affairs Associate
Abbott Laboratories/TheraSense Inc.
Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

Re: k051839
Trade/Device Name: FreeStyle Freedom™ Blood Glucose Monitoring System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: January 20, 2006
Received: January 23, 2006

Dear Ms. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number : K051839

Device Name: FreeStyle Freedom™ Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051839